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CLEARINGHOUSE RULE 95-135

Comments

[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated October 1994.]

1. Statutory Authority

As noted in the analysis to the rule, s. 450.07 (2), Stats., provides that no person may engage in the sale or distribution at wholesale of a prescription drug in Wisconsin without first obtaining a distributor’s license from the Pharmacy Examining Board. Section 450.01 (8), Stats., defines the term “distribute” to mean to deliver, other than by administering or dispensing. The rule-making order creates s. Phar 13.02 (11) (f) to exempt a pharmacy from the distributor licensing requirements if the sales of controlled substances and other prescription drugs to practitioners for dispensing in the practitioners’ offices do not exceed 5% of all such medications distributed and dispensed by the pharmacy during the calendar year. The analysis to the rule states that the Pharmacy Examining Board has applied this policy in the past and is now, in Clearinghouse Rule 95-135, codifying this practice. The board should more fully explain and justify its statutory authority for making an exemption to what appears to be a straightforward prohibition against the unlicensed distribution of prescription drugs in s. 450.07 (2), Stats.

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. In the third sentence of the second paragraph of the department’s analysis, “and” should be deleted and a comma should follow “patients”.

b. In the third sentence of the third paragraph of the department’s analysis, “such as,” should be deleted.

c. As written, s. Phar 6.02 (1m) does not require two pharmacy licenses for a hospital that has a pharmacy area providing outpatient pharmacy services and that is physically separate

from, but contiguous to, the area from which inpatient pharmacy services are provided. If the areas are “noncontiguous” then two licenses are required. Is it clear, in this context, what contiguous and noncontiguous mean? The department’s analysis indicates that the separate license requirement is reasonable “due to the separate record keeping and dispensing requirements, greater public access to the outpatient pharmacy, the need for increased security for the pharmaceutical area, and the existence of a physical separation between the outpatient and inpatient pharmacy locations within such hospitals.” This rationale generally appears to apply to inpatient and outpatient pharmacies located in the same hospital whether or not they are contiguous. Also, the phrase “non contiguous” should be replaced by the phrase “not contiguous” or the word “noncontiguous.” Finally, the word “must” should be replaced by the word “shall.”

d. It is suggested that s. Phar 13.02 (11) (f) be redrafted as follows:

13.02 (11) (f) Distributions to a practitioner for the purpose of general dispensing by the practitioner to his or her patients if all of the following apply:

1. The total number of dosage units of all prescription drugs distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all prescription drugs distributed and dispensed by the pharmacy during the same calendar year.
2. The total number of dosage units of all controlled substances distributed to practitioners by the pharmacy during each calendar year in which the pharmacy is licensed does not exceed 5% of the total number of dosage units of all controlled substances distributed and dispensed by the pharmacy during the same calendar year.